

**REMARKS**

Claims 1, 3-8, 12, 13 and 15 were pending. Applicants hereby cancel claims 12, 13 and 15 without prejudice to Applicants' right to pursue their subject matter in the present application and in related applications. New claims 21-30 are added. Claims 1 and 5-8 are amended without any intent of disclaiming equivalents thereof. Upon entry of this amendment, claims 1, 3-8 and 21-30 will be pending and presented for consideration.

**Claim amendments**

Claim 1 is amended to recite specific RCC disease genes. Support for the amendments is found in the specification as originally filed at least in paragraphs 0012, 0083, 0085, 0086, 0090, 0107, 0133, 0153, 0431, 0432, 0434, 0437, 0438, 0440, 0442, 0444, 0446, 0447, 0448, 0451 and Example 6. Claims 1 and 5-8 are further amended for clarification and consistency.

Support for new claims 21-30 is found in the specification as originally filed at least in Example 6, in particular, paragraph 0614.

Applicants submit that the amendments to claims introduce no new matter.

**Supplemental information disclosure statement**

Applicants submit together with this response a supplemental Information Disclosure Statement and accompanying Form PTO-1449 listing a publication in accordance with the provisions of 37 C.F.R. §§ 1.97 and 1.98 for consideration by the Examiner in connection with the examination of the present patent application.

**Claim rejections under 35 U.S.C. §112, first paragraph, written description**

Claims 1, 3-8, 12, 13 and 15 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office Action alleges that Applicants do not appear to have possession of the entire claimed genus of "RCC disease genes." See, the Office Action, page 7. According to the Office Action, one of ordinary skill in the art would not be able to identify which gene or genes constitute the genus of "RCC disease genes." See, the Office Action, page 7.

Without acquiescing to the rejection and solely to advance prosecution, Applicants have amended the claims to recite specific RCC disease genes that can be used in the claimed method

for diagnosis of renal cell carcinoma (RCC). Independent claim 1, as amended, specifically recites “wherein said one or more RCC disease genes are selected from the group consisting of: eukaryotic elongation factor 1 alpha 2 (EEF1A2); toll-like receptor 2 (TLR2); zinc finger protein 36, C3H type-like 2 (BRF2); lectin, galactoside-binding, soluble, 3 (LGALS3); small nuclear ribonucleoprotein polypeptide G (SNRPG); Ras-induced senescence 1 (DKFZP586E1621); nuclear mitotic apparatus protein 1 (NUMA1); superoxide dismutase 2 (SOD2); aldo-keto reductase family 1, member B1 (AKR1B1); dual specificity phosphatase 6 (DUSP6); SWI/SNF related, matrix associated, actin dependent regulator of chromatin, subfamily e, member 1 (SMARCE1); KIAA0669; MLL septin-like fusion (MSF); interleukin 1 receptor antagonist (IL1RN); prothymosin, alpha (PTMA); KIAA0410; proteasome 26S subunit, non-ATPase, 3 (PSMD3); T54 protein (T54); complement component 1, q subcomponent binding protein (C1QBP); and oxidative-stress responsive 1 (OSR1).” Applicants submit that the recited genes are fully described in the specification. For example, Table 4 and the paragraphs following describe the function and sequence of each of the recited genes. Therefore, Applicants submit that one of ordinary skill in the art, upon reviewing the specification, would readily have concluded that Applicants had possession of the recited RCC disease genes at the time of filing of the present application.

Accordingly, Applicants respectfully submit that the claims as amended fully comply with the written description requirement and request the reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

*Claim rejections under 35 U.S.C. §112, first paragraph, enablement*

Claims 1, 3-8, 12, 13 and 15 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Office Action alleges that the specification, while being enabling for using the combination of 20 genes listed in Table 10 (Example 8), does not reasonably provide enablement for using any other genes or combination of genes and their expression profiles for the purposes of indicating the presence and absence of RCC in human. See, the Office Action, page 10.

Without acquiescing to the rejection and solely to advance prosecution, as discussed above, Applicants have amended the claims to recite specific RCC disease genes that can be used in the claimed method for diagnosis of RCC. Applicants submit that the specification fully

enables the claimed method for diagnosis of RCC using various combinations of the 20 RCC disease genes recited in claim 1. For example, Applicants submit that working examples using the recited RCC disease genes in detecting RCC are provided in Example 6 (paragraphs 0614-0620), Figures 3, 4, 5A and 5B. Applicants therefore respectfully submit that the claims as amended fully comply with the enablement requirement and request the reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

*Claim rejections under 35 U.S.C. §112, second paragraph*

Claims 1, 3-8, 12, 13 and 15 stand rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Office Action alleges that the term “RCC disease genes” recited in claim 1 is unclear as to which specific genes are encompassed by the broad term. The Office Action further alleges the term “the difference or similarity” recited in claim 1 lacks antecedent basis and is indefinite. Without acquiescing to the rejection and solely to advance prosecution, Applicants have amended claim 1 to recite specific genes and to delete the term “the difference or similarity.”

In addition, the Office Action alleges that the term “the expression profile” recited in claims 1, 5 and 8 has insufficient antecedent basis because it is not clear to which expression profile (sample or reference) the term is referring. Without acquiescing to the rejection and solely to advance prosecution, Applicants have amended the claims 1, 5 and 8 to replace “the expression profile” with “the expression profile generated in step (b),” further clarifying to which expression profile the term is referring.

In view of the above amendments, Applicants submit that the scope of the amended is clear and unambiguous. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

**CONCLUSION**

In view of the foregoing, Applicants believe that all rejections have been overcome and claims 1, 3-8 and 21-30 are in condition for allowance. The Examiner is invited to telephone the undersigned attorney to discuss any remaining issues. Early and favorable actions are respectfully solicited.

Respectfully submitted,



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